Complete Summary

GUIDELINE TITLE

Depression in adults with a chronic physical health problem. Treatment and management.

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Mental Health. Depression in adults with a chronic physical health problem. Treatment and management. London (UK): National Institute for Health and Clinical Excellence (NICE); 2009 Oct. 54 p. (Clinical guideline; no. 91).

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Depression
- Chronic physical health problems (such as cancer, heart disease, diabetes, or a musculoskeletal, respiratory, or neurological disorder)

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management

Risk Assessment
Treatment

CLINICAL SPECIALTY

Family Practice
Geriatrics
Internal Medicine
Psychiatry
Psychology

INTENDED USERS

Advanced Practice Nurses
Nurses
Patients
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians

GUIDELINE OBJECTIVE(S)

- To make recommendations for the treatment and management of people with depression and chronic health problems
- The guideline aims to:
    - Improve access and engagement with treatment and services for people with depression and chronic health problems
    - Evaluate the role of specific psychological and psychosocial interventions in the treatment of depression and chronic health problems
    - Evaluate the role of specific pharmacological interventions in the treatment of depression and chronic health problems
    - Evaluate the role of specific service level interventions for people with depression and chronic health problems
    - Integrate the above to provide best-practice advice on the care of people with depression and chronic health problems and their family and carers
    - Promote the implementation of best clinical practice through the development of recommendations tailored to the requirements of the National Health Service (NHS) in England and Wales

TARGET POPULATION

Adults (18 years and older) with a clinical working diagnosis of a depressive disorder and a chronic physical health problem with associated impact on function, which could include, for example, people with cancer, heart disease, neurological disorders, or diabetes, and depression

Note: Groups that will not be covered:

- People with other psychiatric disorders, such as schizophrenia, dementia, or substance misuse
- People with co-morbid physical health problems unexplained by physical pathology

- People with depressive disorders that primarily occur as a side effect of the treatment of a physical disorder

INTERVENTIONS AND PRACTICES CONSIDERED

General Management (Care for All People with Depression)

1. Provision of information and support to patients, carers, and families
2. Obtaining informed consent
3. Comprehensive assessment (symptoms, functional impairment, history, ethnic and cultural background, cognitive impairment, learning disabilities, suicide risk)
4. Delivery of care by competent professionals

Management/Treatment (Stepped Care)

1. Step 1: Recognition, assessment, and initial management
    - Case identification and recognition
    - Risk assessment and monitoring
2. Step 2: Management of persistent subthreshold depressive symptoms or mild to moderate depression
    - Treatment of coexisting anxiety
    - Advice on sleep hygiene
    - Active monitoring
    - Low-intensity psychosocial interventions (e.g., structured group physical activity programme, individual guided self-help based on the principles of cognitive behavioral therapy [CBT])
    - Antidepressant drug treatment, in limited cases
3. Step 3: Management of persistent subthreshold depressive symptoms or mild to moderate depression with inadequate response to initial interventions, and moderate and severe depression
    - Antidepressant drug treatment (selective serotonin reuptake inhibitor [SSRI])
    - High-intensity psychological intervention (e.g., group-based CBT, individual CBT, behavioral couples therapy)
    - Combined antidepressant medication and individual CBT
    - Monitoring the initial phase of drug treatment (e.g., monitoring suicide risk, depressive symptoms, and drug side effects)
    - Stopping or reducing antidepressants
    - Collaborative care
4. Step 4: Management of complex and severe depression
    - Referral to specialist of mental health services

MAJOR OUTCOMES CONSIDERED

- Intermediate or short-term measures
- Mortality
- Morbidity and treatment complications
- Rates of relapse
- Late morbidity and readmission
- Return to work
- Physical and social functioning

- Quality of life
- General health status
- Cost effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Mental Health (NCCMH) on behalf of the National Institute for Health and Clinical Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Methodology

A stepwise, hierarchical approach was taken to locating and presenting evidence to the Guideline Development Group (GDG). The NCCMH developed this process based on methods set out in The Guidelines Manual (NICE, 2007 [see the "Availability of Companion Documents" field]) and after considering recommendations from a range of other sources. These included:

- Clinical Policy and Practice Program of the New South Wales Department of Health (Australia)
- Clinical Evidence online
- The Cochrane Collaboration
- New Zealand Guidelines Group
- NHS Centre for Reviews and Dissemination
- Oxford Centre for Evidence-Based Medicine
- Scottish Intercollegiate Guidelines Network (SIGN)
- United States Agency for Healthcare Research and Quality
- Oxford Systematic Review Development Programme
- Grading of Recommendations: Assessment, Development and Evaluation (GRADE) Working Group

The Review Process

After the scope was finalised, a more extensive search for systematic reviews and published guidelines was undertaken. Existing NICE guidelines were updated where necessary. Other relevant guidelines were assessed for quality using the AGREE instrument (AGREE Collaboration, 2003). The evidence base underlying high-quality existing guidelines was utilised and updated as appropriate (further information about this process can be found in The Guidelines Manual).

At this point, the review team, in conjunction with the GDG, developed an evidence map that detailed all comparisons necessary to answer the clinical questions. The initial approach taken to locating primary-level studies depended on the type of clinical question and availability of evidence. The GDG decided which questions were best addressed by good practice based on expert opinion, which questions were likely to have a good evidence base and which questions were likely to have little or no directly relevant evidence. Recommendations based on good practice were developed by informal consensus of the GDG. For questions with a good evidence base, the review process depended on the type of key question. For questions that were unlikely to have a good evidence base, a brief descriptive review was initially undertaken by a member of the GDG.

Searches for evidence were updated between 6 and 8 weeks before the guideline consultation. After this point, studies were included only if they were judged by the GDG to be exceptional (for example, the evidence was likely to change a recommendation).

The Search Process for Questions Concerning Interventions

For questions related to interventions, the initial evidence base was formed from well-conducted randomized controlled trials (RCTs) that addressed at least one of the clinical questions. Although there are a number of difficulties with the use of RCTs in the evaluation of interventions in mental health, the RCT remains the most important method for establishing treatment efficacy (this is discussed in more detail in appropriate clinical evidence chapters of the full version of the original guideline). For other clinical questions, searches were for the appropriate study design.

Standard mental health related bibliographic databases (i.e., MEDLINE, EMBASE, CINAHL, PsycINFO, Cochrane Library) were used for the initial search for all studies potentially relevant to the guideline. Where the evidence base was large, recent high-quality English-language systematic reviews were used primarily as a source of RCTs (see Appendix 11 for quality criteria used to assess systematic reviews in the full version of the original guideline [see the "Availability of Companion Documents" field]). However, in some circumstances existing data sets were utilised. Where this was the case, data were cross-checked for accuracy before use. New RCTs meeting inclusion criteria set by the GDG were incorporated into the existing reviews and fresh analyses performed.

After the initial search results were scanned liberally to exclude irrelevant papers, the review team used a purpose-built 'study information' database to manage both the included and the excluded studies (eligibility criteria were developed after consultation with the GDG). Double checking of all excluded studies was not done routinely, but a selection of abstracts was checked to ensure reliability of the sifting. For questions without good-quality evidence (after the initial search), a decision was made by the GDG about whether to (a) repeat the search using subject-specific databases (e.g., AMED, ERIC, OpenSIGLE or Sociological Abstracts) (b) conduct a new search for lower levels of evidence or (c) adopt a consensus process. Future guidelines will be able to update and extend the usable evidence base starting from the evidence collected, synthesised and analysed for this guideline.

In addition, searches were made of the reference lists of all eligible systematic reviews and included studies, as well as the list of evidence submitted by stakeholders. Known experts in the field (see Appendix 6 of the full version of the original guideline [see the "Availability of Companion Documents" field]), based both on the references identified in early steps and on advice from GDG members, were sent letters requesting relevant studies that were in the process of being published. In addition, the tables of contents of appropriate journals were periodically checked for relevant studies.

The Search Process for Questions of Diagnosis and Prognosis

For questions related to diagnosis and prognosis, the search process was the same as described above, except that the initial evidence base was formed from studies with the most appropriate and reliable design to answer the particular question. That is, for questions about diagnosis, the initial search was for cross-sectional studies; for questions about prognosis, it was for cohort studies of representative patients. In situations where it was not possible to identify a substantial body of appropriately designed studies that directly addressed each clinical question, a consensus process was adopted.

Search Filters

Search filters developed by the review team consisted of a combination of subject heading and free-text phrases. Specific filters were developed for the guideline topic and, where necessary, for each clinical question. In addition, the review team used filters developed for systematic reviews, RCTs and other appropriate research designs (Appendix 9 in the full version of the original guideline [see the "Availability of Companion Documents" field]).

Study Selection

All primary-level studies included after the first scan of citations were acquired in full and re-evaluated for eligibility at the time they were being entered into the study information database. Appendix 8 of the full version of the original guideline lists the standard inclusion and exclusion criteria. More specific eligibility criteria were developed for each clinical question and are described in the relevant clinical evidence chapters. Eligible systematic reviews and primary-level studies were critically appraised for methodological quality (see Appendix 11 and Appendix 18 of the full version of the original guideline [see the "Availability of Companion Documents" field]). The eligibility of each study was confirmed by at least one member of the appropriate topic group.

For some clinical questions, it was necessary to prioritize the evidence with respect to the UK context (that is, external validity). To make this process explicit, the topic groups took into account the following factors when assessing the evidence:

- Participant factors (for example, gender, age and ethnicity)
- Provider factors (for example, model fidelity, the conditions under which the intervention was performed and the availability of experienced staff to undertake the procedure)

- Cultural factors (for example, differences in standard care and differences in the welfare system)

It was the responsibility of each topic group to decide which prioritisation factors were relevant to each clinical question in light of the UK context and then decide how they should modify their recommendations.

Unpublished Evidence

The GDG used a number of criteria when deciding whether or not to accept unpublished data. First, the evidence must have been accompanied by a trial report containing sufficient detail to properly assess the quality of the data. Second, the evidence must have been submitted with the understanding that data from the study and a summary of the study's characteristics would be published in the full guideline. Therefore, the GDG did not accept evidence submitted as commercial in confidence. However, the GDG recognised that unpublished evidence submitted by investigators might later be retracted by those investigators if the inclusion of such data would jeopardise publication of their research.

Health Economics Search Strategy

For the systematic review of economic evidence the standard mental-health-related bibliographic databases (EMBASE, MEDLINE, CINAHL and PsycINFO) were searched. For these databases, a health economics search filter adapted from the Centre for Reviews and Dissemination at the University of York was used in combination with a general search strategy for depression. Additional searches were performed in specific health economics databases (National Health Service Economic Evaluation Database [NHS EED], Office of Health Economics Health Economic Evaluations Database [OHE HEED]), as well as in the Health Technology Assessment (HTA) database. For the HTA and NHS EED databases, the general strategy for depression was used. OHE HEED was searched using a shorter, database-specific strategy. Initial searches were performed in early 2008. The searches were updated regularly, with the final search performed in January 2009. Details of the search strategy for economic studies on interventions for people with depression and chronic physical health problems are provided in Appendix 13 in the full version of the original guideline (see the "Availability of Companion Documents" field).

In parallel to searches of electronic databases, reference lists of eligible studies and relevant reviews were searched by hand. Studies included in the clinical evidence review were also screened for economic evidence.

The systematic search of the literature identified approximately 35 thousand references (stage 1). Publications that were clearly not relevant were first excluded (stage 2). The abstracts of all potentially relevant publications were then assessed against a set of selection criteria by the health economist (stage 3). Full texts of the studies potentially meeting the selection criteria (including those for which eligibility was not clear from the abstract) were obtained (stage 4). Studies that did not meet the inclusion criteria, were duplicates, were secondary publications to a previous study, or had been updated in more recent publications were subsequently excluded (stage 5). Finally, 3 papers eligible for inclusion were

assessed for study quality and critically appraised (stage 6). The quality assessment was based on the checklists used by the *British Medical Journal* to assist referees in appraising full and partial economic analysis (see Appendix 11 in the full version of the original guideline [see the "Availability of Companion Documents" field]).

Selection Criteria

The following inclusion criteria were applied to select studies identified by the economic searches for further analysis:

- Only papers published in English language were considered
- Studies published from 1998 onwards were included. This date restriction was imposed in order to obtain data relevant to current healthcare settings and costs
- Only studies from Organisation for Economic Co-operation and Development countries were included, as the aim of the review was to identify economic information transferable to the UK context
- Selection criteria based on types of clinical conditions and patients were identical to the clinical literature review
- Studies were included provided that sufficient details regarding methods and results were available to enable the methodological quality of the study to be assessed, and provided that the study's data and results were extractable. Poster presentations and abstracts were excluded from the review
- Full economic evaluations that compared two or more relevant options and considered both costs and consequences (that is, cost–consequence analysis, cost-effectiveness analysis, cost–utility analysis or cost–benefit analysis) were included in the review
- Studies were included if they used clinical effectiveness data from an RCT, a prospective cohort study, or a systematic review and meta-analysis of clinical studies. Studies were excluded if they had a mirror-image or other retrospective design, or if they utilised efficacy data that were based mainly on assumptions

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The quality of the evidence was based on the quality assessment components (study design, limitations to study quality, consistency, directness and any other considerations) and graded using the following definitions:

- **High** = Further research is very unlikely to change our confidence in the estimate of the effect
- **Moderate** = Further research is likely to have an important impact on our confidence in the estimate of the effect and may change the estimate
- **Low** = Further research is very likely to have an important impact on our confidence in the estimate of the effect and is likely to change the estimate
- **Very low** = Any estimate of effect is very uncertain

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Randomized Controlled Trials
Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Mental Health (NCCMH) on behalf of the National Institute for Health and Clinical Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Data Extraction

Study characteristics and outcome data were extracted from all eligible studies, which met the minimum quality criteria, using a bespoke database and Review Manager 4.2.7 (Cochrane Collaboration, 2004) for most outcomes (see Appendix 18 in the full version of the original guideline [see the "Availability of Companion Documents" field]). Study characteristics (see Appendix 20 in the full version of the original guideline) and outcome data on diagnostic accuracy were extracted using Word-based forms and Stata 10 (StataCorp, 2007).

In most circumstances, for a given outcome (continuous and dichotomous), where more than 50% of the number randomised to any group were lost to follow up, the data were excluded from the analysis (except for the outcome 'leaving the study early', in which case, the denominator was the number randomised). Where possible, dichotomous efficacy outcomes were calculated on an intention-to-treat basis (that is, a 'once-randomised-always-analyse' basis). Where there was good evidence that those participants who ceased to engage in the study were likely to have an unfavourable outcome, early withdrawals were included in both the numerator and denominator. Adverse effects were entered into Review Manager as reported by the study authors because it was usually not possible to determine whether early withdrawals had an unfavourable outcome. Where there was limited data for a particular review, the 50% rule was not applied. In these circumstances the evidence was downgraded due to the risk of bias.

Where some of the studies failed to report standard deviations (for a continuous outcome), and where an estimate of the variance could not be computed from other reported data or obtained from the study author, the following approach was taken:

When the number of studies with missing standard deviations was less than a third and when the total number of studies was at least 10, the pooled standard deviation was imputed (calculated from all the other studies in the same meta-analysis that used the same version of the outcome measure). In this case, the appropriateness of the imputation was made by comparing the standardised mean differences (SMDs) of those trials that had reported standard deviations against the hypothetical SMDs of the same trials based on the imputed standard deviations. If they converged, the meta-analytical results were considered to be reliable.

When the conditions above could not be met, standard deviations were taken from another related systematic review (if available). In this case, the results were considered to be less reliable.

The meta-analysis of survival data, such as time to any mood episode, was based on log hazard ratios and standard errors. Since individual patient data were not available in included studies, hazard ratios and standard errors calculated from a Cox proportional hazard model were extracted. Where necessary, standard errors were calculated from confidence intervals or p-value according to standard formulae (see the Cochrane Reviewers' Handbook 4.2.7 [Cochrane Collaboration 2008]). Data were summarised using the generic inverse variance method using Review Manager.

Consultation with another reviewer or members of the Guideline Development Group (GDG) was used to overcome difficulties with coding. Data from studies included in existing systematic reviews were extracted independently by one reviewer and cross-checked with the existing data set. Where possible, two independent reviewers extracted data from new studies. Where double data extraction was not possible, data extracted by one reviewer was checked by the second reviewer. Disagreements were resolved with discussion. Where consensus could not be reached, a third reviewer or GDG members resolved the disagreement. Masked assessment (that is, blind to the journal from which the article comes, the authors, the institution and the magnitude of the effect) was not used since it is unclear that doing so reduces bias.

Synthesising the Evidence

Analysis of Efficacy Studies

Where possible, meta-analysis was used to synthesise the evidence using Review Manager. If necessary, re-analyses of the data or sub-analyses were used to answer clinical questions not addressed in the original studies or reviews.

Dichotomous outcomes were analysed as relative risks (RR) with the associated 95% confidence interval (CI) (for an example, see Figure 1 in the full version of the original guideline [see the "Availability of Companion Documents" field]).

Continuous outcomes were analysed as weighted mean differences (WMD), or as a standardised mean difference (SMD) when different measures were used in different studies to estimate the same underlying effect (for an example, see Figure 2 in the full version of the original guideline). If provided, intention-to-treat

data, using a method such as 'last observation carried forward', were preferred over data from completers.

To check for consistency between studies, both the X^2 test of heterogeneity and a visual inspection of the forest plots were used. The X^2 statistic describes the proportion of total variation in study estimates that is due to heterogeneity. The X^2 statistic was interpreted in the following way:

- >50%: notable heterogeneity (an attempt was made to explain the variation by conducting sub-analyses to examine potential moderators. In addition, studies with effect sizes greater than two standard deviations from the mean of the remaining studies were excluded using sensitivity analyses. If studies with heterogeneous results were found to be comparable with regard to study and participant characteristics, a random-effects model was used to summarise the results. In the random-effects analysis, heterogeneity is accounted for both in the width of CIs and in the estimate of the treatment effect. With decreasing heterogeneity the random-effects approach moves asymptotically towards a fixed-effects model)
- 30 to 50%: moderate heterogeneity (both the chi-squared test of heterogeneity and a visual inspection of the forest plot were used to decide between a fixed and random-effects model)
- <30%: mild heterogeneity (a fixed-effects model was used to synthesise the results)

See section 3.5.4 of the full version of the original guideline (see the "Availability of Companion Documents" field) for further information of data analysis of efficacy studies.

Analysis of Diagnostic Accuracy Studies

The main outcomes extracted for diagnostic accuracy studies were sensitivity, specificity, positive predictive validity and negative predictive validity. These are discussed in detail in section 3.54 of the full version of the original guideline document. In addition, negative likelihood ratios, positive likelihood ratios, and area under the curve are briefly described.

Presenting the Data to the GDG

Study characteristics tables and, where appropriate, forest plots generated with Review Manager 4.2.7 were presented to the GDG in order to prepare a GRADE evidence profile table for each review and to develop recommendations.

Evidence Profile Tables

A GRADE evidence profile was used to summarise, with the exception of diagnostic studies (methods for these studies are at present not sufficiently developed), both the quality of the evidence and the results of the evidence synthesis (see Table 3 in the full version of the original guideline [see the "Availability of Companion Documents" field] for an example of an evidence profile). For each outcome, quality may be reduced depending on the following factors:

- Study design (randomised trial, observational study, or any other evidence)
- Limitations (based on the quality of individual studies; see Appendix 11 of the full version of the original guideline for the quality checklists)
- Inconsistency (see above for how consistency was measured)
- Indirectness (that is, how closely the outcome measures, interventions and participants match those of interest)
- Imprecision (based on the confidence interval around the effect size)

For observational studies, the quality may be increased if there is a large effect, plausible confounding would have changed the effect, or there is evidence of a dose-response gradient (details would be provided under the other considerations column). Each evidence profile also included a summary of the findings: number of patients included in each group, an estimate of the magnitude of the effect, and the overall quality of the evidence for each outcome.

Health Economics Methods

The aim of the health economics was to contribute to the guideline's development by providing evidence on the cost effectiveness of interventions for people with depression and chronic physical health problems covered in the guideline. This was achieved by:

- Systematic literature review of existing economic evidence
- Economic modelling, where economic evidence was lacking or was considered inadequate to inform decisions. If several such areas were identified, they were further categorised on priority by the GDG. This prioritisation was based on anticipated resource implications and quality and availability of clinical data.

Systematic search of the economic literature was undertaken on all areas covered in this guideline.

Moreover, literature on health-related quality of life of people with depression was systematically searched to identify studies reporting appropriate utility weights appropriate for people with co morbid chronic physical health problems that could be utilised in a cost-utility analysis.

In addition to the systematic review of economic literature, the following economic issues were identified by the GDG in collaboration with the health economist as key-priorities for economic modelling in this guideline:

- Cost effectiveness of collaborative care versus usual care in the care of those with moderate and severe depression and chronic physical problems.
- Cost analysis of low-intensity psychological interventions

Data Extraction of Health Economics Data

Details of the search strategy for economic studies on interventions for people with depression and chronic physical health problems are provided in Appendix 13 in the full version of the current guideline (see the "Availability of Companion Documents" field).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus
Informal Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Mental Health (NCCMH) on behalf of the National Institute for Health and Clinical Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

The Guideline Development Group (GDG)

The GDG consisted of professionals in psychiatry, clinical psychology, health psychology, nursing, general practice, occupational therapy, pharmacy, gerontology, cardiology, rheumatology; academic experts in psychiatry and psychology; a service user. The GDG were recruited according to the specification set out in the scope and in line with the process set out in the NICE guideline manual (NICE, 2007). The guideline development process was supported by staff from the NCCMH, who undertook the clinical and health economics literature searches, reviewed and presented the evidence to the GDG, managed the process, and contributed to drafting the guideline.

Guideline Development Group Meetings

GDG meetings were held between 22nd January 2008 and 20th January 2009. During each day-long GDG meeting, in a plenary session, clinical questions and clinical and economic evidence were reviewed and assessed, and recommendations formulated. At each meeting, all GDG members declared any potential conflicts of interest, and service user and carer concerns were routinely discussed as part of a standing agenda.

Topic Groups

The GDG divided its workload along clinically relevant lines to simplify the guideline development process, and GDG members formed smaller topic groups to undertake guideline work in that area of clinical practice. Topic Group 1 covered questions relating to case identification and service configuration. Topic Group 2 covered pharmacology and topic Group 3 covered psychosocial interventions. These groups were designed to efficiently manage the large volume of evidence appraisal prior to presenting it to the GDG as a whole. Each topic group was chaired by a GDG member with expert knowledge of the topic area (one of the healthcare professionals). Topic groups refined the clinical questions, refined the clinical definitions of treatment interventions, reviewed and prepared the evidence with the systematic reviewer before presenting it to the GDG as a whole and helped the GDG to identify further expertise in the topic. Topic group leaders reported the status of the group's work as part of the standing agenda. They also introduced and led the GDG discussion of the evidence review for that topic and

assisted the GDG Chair in drafting the section of the guideline relevant to the work of each topic group.

Service Users and Carers

Individuals with direct experience of services gave an integral service-user focus to the GDG and the guideline. The GDG included a service user. They contributed as full GDG member writing the clinical questions, helping to ensure that the evidence addressed their views and preferences, highlighting sensitive issues and terminology relevant to the guideline, and bringing service-user research to the attention of the GDG. In drafting the guideline, they contributed to writing the guideline's introduction, the Experience of Care chapter and identified recommendations from the service user perspective.

Special Advisors

Special advisors, who had specific expertise in one or more aspects of treatment and management relevant to the guideline, assisted the GDG, commenting on specific aspects of the developing guideline and making presentations to the GDG. Appendix 3 in the full version of the guideline (see the "Availability of Companion Documents" field) lists those who agreed to act as special advisors.

National and International Experts

National and international experts in the area under review were identified through the literature search and through the experience of the GDG members. These experts were contacted to recommend unpublished or soon-to-be published studies in order to ensure up-to-date evidence was included in the development of the guideline. They informed the group about completed trials at the pre-publication stage, systematic reviews in the process of being published, studies relating to the cost effectiveness of treatment and trial data if the GDG could be provided with full access to the complete trial report. Appendix 6 in the full version of the guideline (see the "Availability of Companion Documents" field) lists researchers who were contacted.

Forming the Clinical Summaries and Recommendations

Once the GRADE profile tables relating to a particular clinical question were completed, summary tables incorporating important information from the GRADE profiles were developed (these tables are presented in the evidence chapters of the full version of the original guideline).

The evidence base for depression in people with chronic physical health problems was much more limited than the literature for depression in the general population. In the judgement of the GDG, the nature of depression in the physically ill is not fundamentally different from the broader population who do not experience additional physical illness. Therefore, the GDG decided to draw upon the evidence for depression more generally when forming recommendations. In doing so the GDG worked closely with the GDG which was updating the Depression Guideline and discussed the clinical questions and the outcome of the reviews with the Depression GDG.

Extrapolating evidence from other populations is a complex process therefore it is important to have transparent and clear principles guiding these judgements. Table 4 in the full version of the original guideline (see the "Availability of Companion Documents" field) summarises the main principles used by the GDG and examples of these in the guideline. Where there was evidence in patients with physical health problems that contradicted that found in the general population, then extrapolation did not take place. When there was congruent findings (positive or negative evidence) in both the general population and physically ill population then evidence from both populations was considered. When there was positive evidence in the general population but no clear or robust evidence in the physically ill then decisions on extrapolation were determined by the judgement of the GDG.

Finally, the systematic reviewer in conjunction with the topic group lead produced a clinical evidence summary. Once the GRADE profiles and clinical summaries were finalised and agreed by the GDG and the evidence from depression in the general populations were taken into account, the associated recommendations were drafted, taking into account the trade-off between the benefits and downsides of treatment as well as other important factors. These included economic considerations, values of the development group and society, and the group's awareness of practical issues. The confidence surrounding the evidence in the depression guideline also influenced the GDGs' decision to extrapolate.

Method Used to Answer a Clinical Question in the Absence of Appropriately Designed, High-Quality Research

In the absence of appropriately designed, high-quality research, or where the GDG were of the opinion (on the basis of previous searches or their knowledge of the literature) that there were unlikely to be such evidence, either an informal or formal consensus process was adopted. This process focused on those questions that the GDG considered a priority.

Informal Consensus

The starting point for the process of informal consensus was that a member of the topic group identified, with help from the systematic reviewer, a narrative review that most directly addressed the clinical question. Where this was not possible, a brief review of the recent literature was initiated. This existing narrative review or new review was used as a basis for beginning an iterative process to identify lower levels of evidence relevant to the clinical question and to lead to written statements for the guideline. The process involved a number of steps:

- A description of what is known about the issues concerning the clinical question was written by one of the topic group members.
- Evidence from the existing review or new review was then presented in narrative form to the GDG and further comments were sought about the evidence and its perceived relevance to the clinical question.
- Based on the feedback from the GDG, additional information was sought and added to the information collected. This may include studies that did not directly address the clinical question but were thought to contain relevant data.

- If, during the course of preparing the report, a significant body of primary-level studies (of appropriate design to answer the question) were identified, a full systematic review was done.
- At this time, subject possibly to further reviews of the evidence, a series of statements that directly addressed the clinical question were developed.
- Following this, on occasions and as deemed appropriate by the development group, the report was then sent to appointed experts outside of the GDG for peer review and comment. The information from this process was then fed back to the GDG for further discussion of the statements.
- Recommendations were then developed and could also be sent for further external peer review.
- After this final stage of comment, the statements and recommendations were again reviewed and agreed upon by the GDG.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Economic Evidence

The economic evidence identified by the health economics systematic review is summarized in the respective chapters of the full version of the original guideline, following presentation of the clinical evidence. The references to included studies, as well as the evidence tables with the characteristics and results of economic studies included in the review, are provided in Appendix 17 (in the full version of the original guideline [see the "Availability of Companion Documents" field]). Methods and results of economic modeling are reported in the economic sections of the respective evidence chapters.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline was validated through two consultations.

1. The first draft of the guideline (The full guideline, National Institute for Clinical Excellence (NICE) guideline and Quick Reference Guide) were consulted with Stakeholders and comments were considered by the Guideline Development Group (GDG).
2. The final consultation draft of the full guideline, the NICE guideline and the Information for the Public were submitted to stakeholders for final comments.

The final draft was submitted to the Guideline Review Panel for review prior to publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): This guideline was developed by the National Collaborating Centre for Mental Health (NCCMH) on behalf of the National Institute for Health and Clinical Excellence (NICE). See the "Availability of Companion Documents" field for the full version of this guidance.

Box 1: Depression Definitions (taken from the *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Revision [DSM-IV])

- **Subthreshold depressive symptoms**: Fewer than 5 symptoms of depression.
- **Mild depression**: Few, if any, symptoms in excess of the 5 required to make the diagnosis, and symptoms result in only minor functional impairment.
- **Moderate depression**: Symptoms or functional impairment are between 'mild' and 'severe'.
- **Severe depression**: Most symptoms, and the symptoms markedly interfere with functioning. Can occur with or without psychotic symptoms.

Note that a comprehensive assessment of depression should not rely simply on a symptom count, but should take into account the degree of functional impairment and/or disability (see "Principles of Assessment, Coordination of Care, and Choosing Treatments" below).

Throughout this guideline, the term 'patient' is used to denote a person who has both depression and a chronic physical health problem.

This guideline is published alongside Depression: the treatment and management of depression in adults (see the NGC summary of the NICE clinical guideline), which makes recommendations on the identification, treatment and management of depression in adults aged 18 years and older, in primary and secondary care.

Care of All People with Depression

Providing Information and Support, and Obtaining Informed Consent

When working with patients with depression and a chronic physical health problem and their families or carers:

- Build a trusting relationship and work in an open, engaging and non-judgemental manner
- Explore treatment options for depression in an atmosphere of hope and optimism, explaining the different courses of depression and that recovery is possible
- Be aware that stigma and discrimination can be associated with a diagnosis of depression and take into account how this may affect the patient with a chronic physical health problem

- Ensure that discussions take place in settings in which confidentiality, privacy and dignity are respected.

When working with patients with depression and a chronic physical health problem and their families or carers:

- Provide information appropriate to their level of understanding about the nature of depression and the range of treatments available
- Avoid clinical language without adequate explanation
- Ensure that comprehensive written information is available in the appropriate language and in audio format if possible
- Provide and work proficiently with independent interpreters (that is, someone who is not known to the patient) if needed.

Inform patients with depression and a chronic physical health problem about self-help groups, support groups and other local and national resources for people with depression.

Make all efforts necessary to ensure that a patient with depression and a chronic physical health problem can give meaningful and informed consent before treatment starts. This is especially important when a patient has severe depression or is subject to the Mental Health Act.

Ensure that consent to treatment is based on the provision of clear information (which should also be available in written form) about the intervention, covering:

- What it comprises
- What is expected of the patient while having it
- Likely outcomes (including any side effects)

Supporting Families and Carers

When families or carers are involved in supporting a patient with severe or chronic* depression and a chronic physical health problem, consider:

- Providing written and verbal information on depression and its management, including how families or carers can support the patient
- Offering a carer's assessment of their caring, physical and mental health needs if necessary
- Providing information about local family or carer support groups and voluntary organisations, and helping families or carers to access these
- Negotiating between the patient and their family or carer about confidentiality and the sharing of information.

*__Note__: Depression is described as 'chronic' if symptoms have been present more or less continuously for 2 years or more.

Principles for Assessment, Coordination of Care and Choosing Treatments

When assessing a patient with a chronic physical health problem who may have depression, conduct a comprehensive assessment that does not rely simply on a

symptom count. Take into account both the degree of functional impairment and/or disability associated with the possible depression and the duration of the episode.

In addition to assessing symptoms and associated functional impairment, consider how the following factors may have affected the development, course and severity of a patient's depression:

- Any history of depression and comorbid mental health or physical disorders
- Any past history of mood elevation (to determine if the depression may be part of bipolar disorder) (see the NGC summary of the NICE guideline Bipolar disorder)
- Any past experience of, and response to, treatments
- The quality of interpersonal relationships
- Living conditions and social isolation

Be respectful of, and sensitive to, diverse cultural, ethnic and religious backgrounds when working with patients with depression and a chronic physical health problem, and be aware of the possible variations in the presentation of depression. Ensure competence in:

- Culturally sensitive assessment
- Using different explanatory models of depression
- Addressing cultural and ethnic differences when developing and implementing treatment plans
- Working with families from diverse ethnic and cultural backgrounds.

When assessing a patient with a chronic physical health problem and suspected depression, be aware of any learning disabilities or acquired cognitive impairments, and if necessary consider consulting with a relevant specialist when developing treatment plans and strategies. When providing interventions for patients with a learning disability or acquired cognitive impairment who have a chronic physical health problem and a diagnosis of depression:

- Where possible, provide the same interventions as for other patients with depression
- If necessary, adjust the method of delivery or duration of the intervention to take account of the disability or impairment.

Always ask patients with depression and a chronic physical health problem directly about suicidal ideation and intent. If there is a risk of self-harm or suicide:

- Assess whether the patient has adequate social support and is aware of sources of help
- Arrange help appropriate to the level of risk (see "Risk Assessment and Monitoring" below)
- Advise the patient to seek further help if the situation deteriorates.

Effective Delivery of Interventions for Depression

All interventions for depression should be delivered by competent practitioners. Psychological and psychosocial interventions should be based on the relevant treatment manual(s), which should guide the structure and duration of the intervention. Practitioners should consider using competence frameworks developed from the relevant treatment manual(s) and for all interventions should:

- Receive regular high-quality supervision
- Use routine outcome measures and ensure that the patient with depression is involved in reviewing the efficacy of the treatment
- Engage in monitoring and evaluation of treatment adherence and practitioner competence – for example, by using video and audio tapes, and external audit and scrutiny where appropriate.

Consider providing all interventions in the preferred language of the patient with depression and a chronic physical health problem where possible.

Where a patient's management is shared between primary and secondary care, there should be clear agreement between practitioners (especially the patient's GP) on the responsibility for the monitoring and treatment of that patient. The treatment plan should be shared with the patient and, where appropriate, with their family or carer.

If a patient's chronic physical health problem restricts their ability to engage with a preferred psychosocial or psychological treatment for depression, consider alternatives in discussion with the patient, such as antidepressants or delivery of psychosocial or psychological interventions by telephone if mobility or other difficulties prevent face-to face contact. (See relevant treatment recommendations below.)

Stepped Care

The stepped-care model provides a framework in which to organize the provision of services, and supports patients, carers and practitioners in identifying and accessing the most effective interventions (see figure below). In stepped care the least intrusive, most effective intervention is provided first; if a patient does not benefit from the intervention initially offered, or declines an intervention, they should be offered an appropriate intervention from the next step.

Figure 1: The Stepped-Care Model

Focus of the Intervention	Nature of the Intervention
STEP 4: Severe and complex[a] depression; risk to life; severe self-neglect	Medication, high-intensity psychological interventions, electroconvulsive therapy, crisis service, combined treatments, multiprofessional and inpatient care
STEP 3: Persistent subthreshold depressive symptoms or mild to moderate depression with inadequate response to initial interventions;	Medication, high-intensity psychological interventions, combined treatments, collaborative care[b] and referral for further assessment and interventions

Focus of the Intervention	Nature of the Intervention
moderate and severe depression	
STEP 2: Persistent subthreshold depressive symptoms; mild to moderate depression	Low-intensity psychosocial interventions, psychological interventions, medication and referral for further assessment and interventions
STEP 1: All known and suspected presentations of depression	Assessment, support, psychoeducation, active monitoring and referral for further assessment and interventions

[a]Complex depression includes depression that shows an inadequate response to multiple treatments, is complicated by psychotic symptoms, and/or is associated with significant psychiatric comorbidity or psychosocial factors.
[b]Only for depression where the person also has a chronic physical health problem and associated functional impairment

Step 1: Recognition, Assessment and Initial Management in Primary Care and General Hospital Settings

The recommendations in this section are primarily for practitioners working in primary care and in general hospital settings. Practitioners should be aware that patients with a chronic physical health problem are at a high risk of depression, particularly where there is functional impairment.

Case Identification and Recognition

Be alert to possible depression (particularly in patients with a past history of depression or a chronic physical health problem with associated functional impairment) and consider asking patients who may have depression two questions, specifically:

- During the last month, have you often been bothered by feeling down, depressed or hopeless?
- During the last month, have you often been bothered by having little interest or pleasure in doing things?

If a patient with a chronic physical health problem answers 'yes' to either of the depression identification questions but the practitioner is not competent to perform a mental health assessment, they should refer the patient to an appropriate professional. If this professional is not the patient's general practitioner (GP), inform the GP of the referral.

If a patient with a chronic physical health problem answers 'yes' to either of the depression identification questions, a practitioner who is competent to perform a mental health assessment should:

- Ask three further questions to improve the accuracy of the assessment of depression, specifically:

    - During the last month, have you often been bothered by feelings of worthlessness?
    - During the last month, have you often been bothered by poor concentration?
    - During the last month, have you often been bothered by thoughts of death?
- Review the patient's mental state and associated functional, interpersonal and social difficulties
- Consider the role of both the chronic physical health problem and any prescribed medication in the development or maintenance of the depression
- Ascertain that the optimal treatment for the physical health problem is being provided and adhered to, seeking specialist advice if necessary.

When assessing a patient with suspected depression, consider using a validated measure (for example, for symptoms, functions and/or disability) to inform and evaluate treatment.

For patients with significant language or communication difficulties, for example patients with sensory impairments or a learning disability, consider using the Distress Thermometer** and/or asking a family member or carer about the patient's symptoms to identify possible depression. If a significant level of distress is identified, investigate further.

****Note**: The Distress Thermometer is a single-item question screen that will identify distress coming from any source. The patient places a mark on the scale answering: 'How distressed have you been during the past week on a scale of 0 to 10?' Scores of 4 or more indicate a significant level of distress that should be investigated further. (Roth AJ, Kornblith AB, Batel-Copel L et al. [1998] Rapid screening for psychologic distress in men with prostate carcinoma: a pilot study. Cancer 82: 1904–8)

Risk Assessment and Monitoring

If a patient with depression and a chronic physical health problem presents considerable immediate risk to themselves or others, refer them urgently to specialist mental health services.

Advise patients with depression and a chronic physical health problem of the potential for increased agitation, anxiety and suicidal ideation in the initial stages of treatment for depression; actively seek out these symptoms and:

- Ensure that the patient knows how to seek help promptly
- Review the patient's treatment if they develop marked and/or prolonged agitation.

Advise a patient with depression and a chronic physical health problem, and their family or carer, to be vigilant for mood changes, negativity and hopelessness, and suicidal ideation, and to contact their practitioner if concerned. This is particularly important during high-risk periods, such as starting or changing treatment and at times of increased personal stress.

If a patient with depression and a chronic physical health problem is assessed to be at risk of suicide:

- Take into account toxicity in overdose if an antidepressant is prescribed or the patient is taking other medication; if necessary, limit the amount of drug(s) available
- Consider increasing the level of support, such as more frequent direct or telephone contacts
- Consider referral to specialist mental health services.

Step 2: Recognized Depression in Primary Care and General Hospital Settings – Persistent Subthreshold Depressive Symptoms or Mild to Moderate Depression

General Measures

Depression with Anxiety

When depression is accompanied by symptoms of anxiety, the first priority should usually be to treat the depression. When the patient has an anxiety disorder and comorbid depression or depressive symptoms, consult the NICE guideline for the relevant anxiety disorder (see section 6 of the short version of the original guideline document) and consider treating the anxiety disorder first (since effective treatment of the anxiety disorder will often improve the depression or the depressive symptoms).

Sleep Hygiene

Offer patients with depression and a chronic physical health problem advice on sleep hygiene if needed, including:

- Establishing regular sleep and wake times
- Avoiding excess eating, smoking or drinking alcohol before sleep
- Creating a proper environment for sleep
- Taking regular physical exercise where this is possible for the patient

Active Monitoring

For patients who, in the judgement of the practitioner, may recover with no formal intervention, or patients with mild depression who do not want an intervention, or patients with subthreshold depressive symptoms who request an intervention:

- Discuss the presenting problem(s) and any concerns that the patient may have about them
- Provide information about the nature and course of depression
- Arrange a further assessment, normally within 2 weeks
- Make contact if the patient does not attend follow-up appointments

Low-Intensity Psychosocial Interventions

For patients with persistent subthreshold depressive symptoms or mild to moderate depression and a chronic physical health problem, and for patients with subthreshold depressive symptoms that complicate the care of the chronic

physical health problem, consider offering one or more of the following interventions, guided by the patient's preference:

- A structured group physical activity programme
- A group-based peer support (self-help) programme
- Individual guided self-help based on the principles of cognitive behavioural therapy (CBT)
- Computerised cognitive behavioural therapy (CCBT)

Delivery of Low-Intensity Psychosocial Interventions

Physical activity programmes for patients with persistent subthreshold depressive symptoms or mild to moderate depression and a chronic physical health problem, and for patients with subthreshold depressive symptoms that complicate the care of the chronic physical health problem, should:

- Be modified (in terms of the duration of the programme and frequency and length of the sessions) for different levels of physical ability as a result of the particular chronic physical health problem, in liaison with the team providing care for the physical health problem
- Be delivered in groups with support from a competent practitioner
- Consist typically of two or three sessions per week of moderate duration (45 minutes to 1 hour) over 10 to 14 weeks (average 12 weeks)
- Be coordinated or integrated with any rehabilitation programme for the chronic physical health problem.

Group-based peer support (self-help) programs for patients with persistent subthreshold depressive symptoms or mild to moderate depression and a chronic physical health problem, and for patients with subthreshold depressive symptoms that complicate the care of the chronic physical health problem, should:

- Be delivered to groups of patients with a shared chronic physical health problem
- Focus on sharing experiences and feelings associated with having a chronic physical health problem
- Be supported by practitioners who should:
    - Facilitate attendance at the meetings
    - Have knowledge of the patients' chronic physical health problem and its relationship to depression
    - Review the outcomes of the intervention with the individual patients
- Consist typically of one session per week delivered over a period of 8 to 12 weeks.

Individual guided self-help programmes based on the principles of CBT (and including behavioral activation and problem-solving techniques) for patients with persistent subthreshold depressive symptoms or mild to moderate depression and a chronic physical health problem, and for patients with subthreshold depressive symptoms that complicate the care of the chronic physical health problem, should:

- Include the provision of written materials of an appropriate reading age (or alternative media to support access)

- Be supported by a trained practitioner, who typically facilitates the self-help programme and reviews progress and outcome
- Consist of up to six to eight sessions (face-to-face and via telephone) normally taking place over 9 to 12 weeks, including follow-up.

CCBT for patients with persistent subthreshold depressive symptoms or mild to moderate depression and a chronic physical health problem, and for patients with subthreshold depressive symptoms that complicate the care of the chronic physical health problem, should:

- Be provided via a stand-alone computer-based or web-based programme
- Include an explanation of the CBT model, encourage tasks between sessions, and use thought-challenging and active monitoring of behaviour, thought patterns and outcomes
- Be supported by a trained practitioner, who typically provides limited facilitation of the programme and reviews progress and outcome
- Typically take place over 9 to 12 weeks, including follow-up

Drug Treatment

Do not use antidepressants routinely to treat subthreshold depressive symptoms or mild depression in patients with a chronic physical health problem (because the risk–benefit ratio is poor), but consider them for patients with:

- A past history of moderate or severe depression **or**
- Mild depression that complicates the care of the physical health problem **or**
- Initial presentation of subthreshold depressive symptoms that have been present for a long period (typically at least 2 years) **or**
- Subthreshold depressive symptoms or mild depression that persist(s) after other interventions.

Although there is evidence that St John's wort may be of benefit in mild or moderate depression, practitioners should:

- Not prescribe or advise its use by patients with depression and a chronic physical health problem because of uncertainty about appropriate doses, persistence of effect, variation in the nature of preparations and potential serious interactions with other drugs (including oral contraceptives, anticoagulants and anticonvulsants)
- Advise patients with depression of the different potencies of the preparations available and of the potential serious interactions of St John's wort with other drugs.

Step 3: Recognized Depression in Primary Care and General Hospital Settings – Persistent Subthreshold Depressive Symptoms or Mild to Moderate Depression with Inadequate Response to Initial Interventions, and Moderate and Severe Depression

Treatment Options

For patients with persistent subthreshold depressive symptoms or mild to moderate depression and a chronic physical health problem who have not benefited from a low-intensity psychosocial intervention, discuss the relative merits of different interventions with the patient and provide:

- An antidepressant (normally a selective serotonin reuptake inhibitor [SSRI]) or
- One of the following high-intensity psychological interventions
    - Group-based CBT **or**
    - Individual CBT for patients who decline group-based CBT or for whom it is not appropriate, or where a group is not available **or**
    - Behavioral couples therapy for people who have a regular partner and where the relationship may contribute to the development or maintenance of depression, or where involving the partner is considered to be of potential therapeutic benefit.

For patients with initial presentation of moderate depression and a chronic physical health problem, offer the following choice of high-intensity psychological interventions:

- Group-based CBT **or**
- Individual CBT for patients who decline group-based CBT or for whom it is not appropriate, or where a group is not available *or*
- Behavioural couples therapy for people who have a regular partner and where the relationship may contribute to the development or maintenance of depression, or where involving the partner is considered to be of potential therapeutic benefit.

For patients with initial presentation of severe depression and a chronic physical health problem, consider offering a combination of individual CBT and an antidepressant.

The choice of intervention should be influenced by the:

- Duration of the episode of depression and the trajectory of symptoms
- Previous course of depression and response to treatment
- Likelihood of adherence to treatment and any potential adverse effects
- Course and treatment of the chronic physical health problem
- Patient's treatment preference and priorities.

Antidepressant Drugs

Choice of Antidepressants

Note: For additional considerations on the use of antidepressants and other medications (including the assessment of the relative risks and benefits) for women who may become pregnant, please refer to the British National Formulary (BNF) and individual drug Summaries of Product Characteristics (SPCs). For women in the antenatal and postnatal periods, see also NICE clinical guideline 45 'Antenatal and postnatal mental health'.

When an antidepressant is to be prescribed for a patient with depression and a chronic physical health problem, take into account the following:

- The presence of additional physical health disorders
- The side effects of antidepressants, which may impact on the underlying physical disease (in particular, SSRIs may result in or exacerbate hyponatraemia, especially in older people)
- That there is no evidence as yet supporting the use of specific antidepressants for patients with particular chronic physical health problems
- Interactions with other medications.

When an antidepressant is to be prescribed, be aware of drug interactions and:

- Refer to appendix 1 of the BNF (available from www.bnf.org) and the table of interactions in appendix 16 of the original full guideline for information
- Seek specialist advice if there is uncertainty
- If necessary, refer the patient to specialist mental health services for continued prescribing.

First prescribe an SSRI in generic form unless there are interactions with other drugs; consider using citalopram or sertraline because they have less propensity for interactions.

When prescribing antidepressants, be aware that:

- Dosulepin should not be prescribed
- Non-reversible monoamine oxidase inhibitors (MAOIs; for example, phenelzine), combined antidepressants and lithium augmentation of antidepressants should normally be prescribed only by specialist mental health professionals.

Take into account toxicity in overdose when choosing an antidepressant for patients at significant risk of suicide. Be aware that:

- Compared with other equally effective antidepressants recommended for routine use in primary care, venlafaxine is associated with a greater risk of death from overdose
- Tricyclic antidepressants (TCAs), except for lofepramine, are associated with the greatest risk in overdose.

Interactions of SSRIs with Other Medication

See appendix 1 of the BNF and appendix 16 of the full version of the original guideline (see the "Availability of Companion Documents" field) for information on drug interactions.

Do not normally offer SSRIs to patients taking non-steroidal anti-inflammatory drugs (NSAIDs) because of the increased risk of gastrointestinal bleeding. Consider offering an antidepressant with a lower propensity for, or a different range of, interactions, such as mianserin, mirtazapine, moclobemide, reboxetine or trazodone.

If no suitable alternative antidepressant can be identified, SSRIs may be prescribed at the same time as NSAIDs if gastroprotective medicines (for example, proton-pump inhibitors) are also offered.

Do not normally offer SSRIs to patients taking warfarin or heparin because of their anti-platelet effect.

Use SSRIs with caution in patients taking aspirin. When aspirin is used as a single agent, consider alternatives that may be safer, such as trazodone, mianserin or reboxetine.

If no suitable alternative antidepressant can be identified, SSRIs may be prescribed at the same time as aspirin if gastroprotective medicines (for example, proton-pump inhibitors) are also offered.

Consider offering mirtazapine to patients taking heparin, aspirin or warfarin (but note that when taken with warfarin, the international normalised ratio [INR] may increase slightly).

Do not offer SSRIs to patients receiving 'triptan' drugs for migraine. Offer a safer alternative such as mirtazapine, trazodone, mianserin or reboxetine.

Do not normally offer SSRIs at the same time as monoamine oxidase B (MAO-B) inhibitors such as selegiline and rasagiline. Offer a safer alternative such as mirtazapine, trazodone, mianserin or reboxetine.

Do not normally offer fluvoxamine to patients taking theophylline, clozapine, methadone or tizanidine. Offer a safer alternative such as sertraline or citalopram.

Offer sertraline as the preferred antidepressant for patients taking flecainide or propafenone, although mirtazapine and moclobemide may also be used.

Do not offer fluoxetine or paroxetine to patients taking atomoxetine. Offer a different SSRI.

Starting Treatment

When prescribing antidepressants, explore any concerns the patient with depression and a chronic physical health problem has about taking medication, explain fully the reasons for prescribing, and provide information about taking antidepressants, including:

- The gradual development of the full antidepressant effect
- The importance of taking medication as prescribed and the need to continue treatment after remission
- Potential side effects
- The potential for interactions with other medications
- The risk and nature of discontinuation symptoms with all antidepressants, particularly with drugs with a shorter half-life (such as paroxetine and venlafaxine), and how these symptoms can be minimised
- The fact that addiction does not occur with antidepressants.

Offer written information appropriate to the patient's needs.

Prescribe antidepressant medication at a recognised therapeutic dose for patients with depression and a chronic physical health problem (that is, avoid the tendency to prescribe at subtherapeutic doses in these patients).

For patients started on antidepressants who are not considered to be at increased risk of suicide, normally see them after 2 weeks. See them regularly thereafter, for example at intervals of 2 to 4 weeks in the first 3 months, and then at longer intervals if response is good.

A patient with depression started on antidepressants who is considered to present an increased suicide risk or is younger than 30 years (because of the potential increased prevalence of suicidal thoughts in the early stages of antidepressant treatment for this group) should normally be seen after 1 week and frequently thereafter as appropriate until the risk is no longer considered clinically important.

If a patient with depression and a chronic physical health problem develops side effects early in antidepressant treatment, provide appropriate information and consider one of the following strategies:

- Monitor symptoms closely where side effects are mild and acceptable to the patient **or**
- Stop the antidepressant or change to a different antidepressant if the patient prefers **or**
- In discussion with the patient, consider short-term concomitant treatment with a benzodiazepine if anxiety, agitation and/or insomnia are problematic, but:
    - Do not offer benzodiazepines to patients with chronic symptoms of anxiety
    - Use benzodiazepines with caution in patients at risk of falls
    - In order to prevent the development of dependence, do not use benzodiazepines for longer than 2 weeks.

Continuing Treatment

Support and encourage a patient with a chronic physical health problem who has benefited from taking an antidepressant to continue medication for at least 6 months after remission of an episode of depression. Discuss with the patient that:

- This greatly reduces the risk of relapse
- Antidepressants are not associated with addiction.

Review with the patient with depression and a chronic physical health problem the need for continued antidepressant treatment beyond 6 months after remission, taking into account:

- The number of previous episodes of depression
- The presence of residual symptoms
- Concurrent physical health problems and psychosocial difficulties.

Failure of Treatment to Provide Benefit

More detailed advice on switching, sequencing, augmenting and combining antidepressants can be found in the section "Sequencing Treatments after Initial Inadequate Response" in the NGC summary of the NICE guideline, Depression: the treatment and management of depression in adults (update). The recommendations below should be considered alongside recommendations in the section 'Interactions of SSRIs with other medication' in the current guideline.

If the patient's depression shows no improvement after 2 to 4 weeks with the first antidepressant, check that the drug has been taken regularly and in the prescribed dose.

If response is absent or minimal after 3 to 4 weeks of treatment with a therapeutic dose of an antidepressant, increase the level of support (for example, by weekly face-to-face or telephone contact) and consider:

- Increasing the dose in line with the SPC if there are no significant side effects **or**
- Switching to another antidepressant as described in the section "Sequencing Treatments after Initial Inadequate Response" of the Depression guideline (CG90) if there are side effects or if the patient prefers.

If the patient's depression shows some improvement by 4 weeks, continue treatment for another 2 to 4 weeks. Consider switching to another antidepressant as described in the section "Sequencing Treatments after Initial Inadequate Response" of the NGC summary of the NICE guideline, Depression: the treatment and management of depression in adults (update) if:

- Response is still not adequate **or**
- There are side effects **or**
- The patient prefers to change treatment.

When switching from one antidepressant to another, be aware of:

- The need for gradual and modest incremental increases in dose
- Interactions between antidepressants
- The risk of serotonin syndrome when combinations of serotonergic antidepressants are prescribed (features of serotonin syndrome include confusion, delirium, shivering, sweating, changes in blood pressure and myoclonus).

If an antidepressant has not been effective or is poorly tolerated:

- Consider offering other treatment options, including high-intensity psychological treatments (see below)
- Prescribe another single antidepressant (which can be from the same class) if the decision is made to offer a further course of antidepressants.

Stopping or Reducing Antidepressants

Advise patients with depression and a chronic physical health problem who are taking antidepressants that discontinuation symptoms may occur on stopping, missing doses or, occasionally, on reducing the dose of the drug. Explain that symptoms are usually mild and self-limiting over about 1 week, but can be severe, particularly if the drug is stopped abruptly. (Discontinuation symptoms include increased mood change, restlessness, difficulty sleeping, unsteadiness, sweating, abdominal symptoms and altered sensations.)

When stopping an antidepressant, gradually reduce the dose, normally over a 4-week period, although some patients may require longer periods, particularly with drugs with a shorter half-life (such as paroxetine and venlafaxine). This is not required with fluoxetine because of its long half-life.

Inform the patient that they should seek advice from their practitioner if they experience significant discontinuation symptoms. If discontinuation symptoms occur:

- Monitor symptoms and reassure the patient if symptoms are mild
- Consider reintroducing the original antidepressant at the dose that was effective (or another antidepressant with a longer half-life from the same class) if symptoms are severe, and reduce the dose gradually while monitoring symptoms.

Psychological Interventions

Delivering High-Intensity Psychological Interventions

For all high-intensity psychological interventions, the duration of treatment should normally be within the limits indicated in this guideline. As the aim of treatment is to obtain significant improvement or remission the duration of treatment may be:

- Reduced if remission has been achieved
- Increased if progress is being made, and there is agreement between the practitioner and the patient with depression that further sessions would be beneficial (for example, if there is a comorbid personality disorder or psychosocial factors that impact on the patient's ability to benefit from treatment).

Group-based CBT for patients with depression and a chronic physical health problem should be:

- Delivered in groups (typically of between six and eight patients) with a common chronic physical health problem
- Typically delivered over a period of 6 to 8 weeks.

Individual CBT for patients with moderate depression and a chronic physical health problem should be:

- Delivered until the symptoms of depression have remitted (over a period that is typically 6 to 8 weeks and should not normally exceed 16 to 18 weeks)

- Followed up by two further sessions in the 6 months after the end of treatment, especially if treatment was extended.

Individual CBT for patients with severe depression and a chronic physical health problem should be:

- Delivered until the symptoms of depression have remitted (over a period that is typically 16 to 18 weeks)
- Focused in the initial sessions (which typically should take place twice weekly for the first 2 to 3 weeks) on behavioral activation
- Followed up by two or three further sessions in the 12 months after the end of treatment.

Behavioral couples therapy for depression should normally be based on behavioural principles, and an adequate course of therapy should be 15 to 20 sessions over 5 to 6 months.

Collaborative Care

Collaborative care, which should form part of a well-developed stepped-care programme, could be provided at the primary or secondary care level. The interventions, which involve all sectors of care, require a coordinated approach to mental and physical healthcare, as well as a dedicated coordinator of the intervention located in and receiving support from a multi-professional team, joint determination of the plan of care, and long-term coordination and follow-up.

Consider collaborative care for patients with moderate to severe depression and a chronic physical health problem with associated functional impairment whose depression has not responded to initial high-intensity psychological interventions, pharmacological treatment or a combination of psychological and pharmacological interventions.

Collaborative care for patients with depression and a chronic physical health problem should normally include:

- Case management which is supervised and has support from a senior mental health professional
- Close collaboration between primary and secondary physical health services and specialist mental health services
- A range of interventions consistent with those recommended in this guideline, including patient education, psychological and pharmacological interventions, and medication management
- Long-term coordination of care and follow-up.

Step 4: Complex and Severe Depression

Practitioners providing treatment in specialist mental health services for patients with complex and severe depression and a chronic physical health problem should:

- Refer to the NGC summary of the NICE guideline, Depression: the treatment and management of depression in adults (update).
- Be aware of the additional drug interactions associated with the treatment of patients with both depression and a chronic physical health problem
- Work closely and collaboratively with the physical health services.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Recommendations are based on clinical and cost effectiveness evidence, and where this is insufficient, the Guideline Development Group (GDG) used all available information sources and experience to make consensus recommendations.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate treatment and management of depression in adults with a chronic physical health problem
- Improved depression care is thought to produce other health benefits, such as improved functioning and physical outcomes.
- For all depression outcomes, there was a demonstrable increase in benefits when collaborative care was compared with standard care as opposed to enhanced standard care. Both response and remission rates increased in the standard care condition.

POTENTIAL HARMS

- The side effects of antidepressants, which may impact on the underlying physical disease (in particular, selective serotonin reuptake inhibitors [SSRIs] may result in or exacerbate hyponatraemia, especially in older people)
- Interactions of antidepressants with other medications (see "Interactions of SSRIs with other medication" in the "Major Recommendations" field of this summary; refer also to appendix 1 of the British National Formulary [BNF] and the table of interaction in appendix 16 of the full version of the original guideline [see the "Availability of Companion Documents" field] for more information on drug interactions)
- Toxicity in overdose when choosing an antidepressant at significant risk of suicide
- Discontinuation symptoms may occur on stopping, missing does, or, occasionally, on reducing doses of antidepressant medication.

CONTRAINDICATIONS

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Tricyclic antidepressants (TCAs) are likely to be pro-arrhythmic in patients with recent myocardial infarction and their use is contraindicated.

QUALIFYING STATEMENTS

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- This guidance represents the view of the National Institute for Health and Clinical Excellence (NICE), which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summary of product characteristics of any drugs they are considering.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The Healthcare Commission assesses the performance of National health Service (NHS) organisations in meeting core and developmental standards set by the Department of Health in 'Standards for better health' (available from www.dh.gov.uk). Implementation of clinical guidelines forms part of the developmental standard D2. Core standard C5 says that national agreed guidance should be taken into account when NHS organisations are planning and delivering care.

The National Institute for Health and Clinical Excellence (NICE) has developed tools to help organisations implement this guidance. These are available on the NICE website (http://guidance.nice.org.uk/CG91; see also the "Availability of Companion Documents" field).

Key Priorities for Implementation

Principles for Assessment

- When assessing a patient with a chronic physical health problem who may have depression, conduct a comprehensive assessment that does not rely simply on a symptom count. Take into account both the degree of functional

impairment and/or disability associated with the possible depression and the duration of the episode.

Effective Delivery of Interventions for Depression

- All interventions for depression should be delivered by competent practitioners. Psychological and psychosocial interventions should be based on the relevant treatment manual(s), which should guide the structure and duration of the intervention. Practitioners should consider using competence frameworks developed from the relevant treatment manual(s) and for all interventions should:
    - Receive regular high-quality supervision
    - Use routine outcome measures and ensure that the patient with depression is involved in reviewing the efficacy of the treatment
    - Engage in monitoring and evaluation of treatment adherence and practitioner competence – for example, by using video and audio tapes, and external audit and scrutiny where appropriate.

Case Identification and Recognition

- Be alert to possible depression (particularly in patients with a past history of depression or a chronic physical health problem with associated functional impairment) and consider asking patients who may have depression two questions, specifically:
    - During the last month, have you often been bothered by feeling down, depressed or hopeless?
    - During the last month, have you often been bothered by having little interest or pleasure in doing things?

Low-Intensity Psychosocial Interventions

- For patients with persistent subthreshold depressive symptoms or mild to moderate depression and a chronic physical health problem, and for patients with subthreshold depressive symptoms that complicate the care of the chronic physical health problem, consider offering one or more of the following interventions, guided by the patient's preference:
    - A structured group physical activity programme
    - A group-based peer support (self-help) programme
    - Individual guided self-help based on the principles of cognitive behavioural therapy (CBT)
    - Computerised cognitive behavioural therapy (CCBT)

Treatment for Moderate Depression

- For patients with initial presentation of moderate depression and a chronic physical health problem, offer the following choice of high-intensity psychological interventions:
    - Group-based CBT **or**
    - Individual CBT for patients who decline group-based CBT or for whom it is not appropriate, or where a group is not available **or**
    - Behavioural couples therapy for people who have a regular partner and where the relationship may contribute to the development or

maintenance of depression, or where involving the partner is considered to be of potential therapeutic benefit.

Antidepressant Drugs

- Do not use antidepressants routinely to treat subthreshold depressive symptoms or mild depression in patients with a chronic physical health problem (because the risk–benefit ratio is poor), but consider them for patients with:
    - A past history of moderate or severe depression **or**
    - Mild depression that complicates the care of the physical health problem **or**
    - Initial presentation of subthreshold depressive symptoms that have been present for a long period (typically at least 2 years) **or**
    - Subthreshold depressive symptoms or mild depression that persist(s) after other interventions.
- When an antidepressant is to be prescribed for a patient with depression and a chronic physical health problem, take into account the following:
    - The presence of additional physical health disorders
    - The side effects of antidepressants, which may impact on the underlying physical disease (in particular, selective serotonin reuptake inhibitors [SSRIs] may result in or exacerbate hyponatraemia, especially in older people)
    - That there is no evidence as yet supporting the use of specific antidepressants for patients with particular chronic physical health problems
    - Interactions with other medications.

Collaborative Care

- Consider collaborative care for patients with moderate to severe depression and a chronic physical health problem with associated functional impairment whose depression has not responded to initial high-intensity psychological interventions, pharmacological treatment or a combination of psychological and pharmacological interventions

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Foreign Language Translations
Patient Resources
Quick Reference Guides/Physician Guides
Resources
Slide Presentation
Staff Training/Competency Material

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Mental Health. Depression in adults with a chronic physical health problem. Treatment and management. London (UK): National Institute for Health and Clinical Excellence (NICE); 2009 Oct. 54 p. (Clinical guideline; no. 91).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2009 Oct

GUIDELINE DEVELOPER(S)

National Collaborating Centre for Mental Health - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Guideline Development Group

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Declarations of Interests by Guideline Development Group (GDG) Members

With a range of practical experience relevant to the treatment and management of depression in adults with chronic physical health problems in the GDG, members were appointed because of their understanding and expertise in

healthcare for people with depression and chronic physical health problems and support for their families/carers, including: scientific issues; health research; the delivery and receipt of healthcare, along with the work of the healthcare industry; and the role of professional organisations and organisations for people with depression and chronic physical health problems and their families/carers.

To minimise and manage any potential conflicts of interest, and to avoid any public concern that commercial or other financial interests have affected the work of the GDG and influenced guidance, members of the GDG must declare as a matter of public record any interests held by themselves or their families which fall under specified categories. These categories include any relationships they have with the healthcare industries, professional organisations and organisations for people with depression and chronic physical health problems and their families/carers.

Individuals invited to join the GDG were asked to declare their interests before being appointed. To allow the management of any potential conflicts of interest that might arise during the development of the guideline, GDG members were also asked to declare their interests at each GDG meeting throughout the guideline development process. The interests of all the members of the GDG are listed in Appendix 2 of the full version of the original guideline, including interests declared prior to appointment and during the guideline development process.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Depression with a chronic physical health problem. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence; 2009 Oct. 10 p. (Clinical guideline; no. 91). Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.

Print copies: Available from NICE publications on 0845 003 7783 or email publications@nice.org.uk and quote: N2018. 11 Strand, London, WC2N 5HR.

The following are also available:

- Depression with a chronic physical health problem. Full guideline. London (UK): National Institute for Health and Clinical Excellence (NICE); 2009 Oct. 397 p. (Clinical guideline; no. 91). Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

- Depression with a chronic physical health problem. Appendices to full version. London (UK): National Institute for Health and Clinical Excellence; 2009 Oct. Various p. (Clinical guideline; no. 91). Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- Depression with a chronic physical health problem. Costing statement. London (UK): National Institute for Health and Clinical Excellence; 2009 Oct. 10 p. (Clinical guideline; no. 91). Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- Depression with a chronic physical health problem. Slide set. London (UK): National Institute for Health and Clinical Excellence; 2009. 22 p. (Clinical guideline; no. 91). Electronic copies: Available from the NICE Web site.
- Depression with a chronic physical health problem. Audit support. London (UK): National Institute for Health and Clinical Excellence; 2010. 21 p. (Clinical guideline; no. 91). Electronic copies: Available from the NICE Web site.
- Depression in adults with a chronic health problem. Online educational tool. London (UK): National Institute for Health and Clinical Excellence; 2009. Various p. (Clinical guideline; no. 91). Electronic copies: Available from the NICE Web site.
- The guidelines manual 2009. London (UK): National Institute for Health and Clinical Excellence (NICE); 2009 Jan. Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.

PATIENT RESOURCES

The following is available:

- Depression with a chronic physical health problem. Understanding NICE guidance - Information for people who use NHS services. London (UK): National Institute for Health and Clinical Excellence; 2009 Oct. 20 p. (Clinical guideline; no. 91). Electronic copies: Available in English and Welsh from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from NICE publications on 0845 003 7783 or email publications@nice.org.uk and quote: N2019. 11 Strand, London, WC2N 5HR.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

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